and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0138. The approval expires on June 30, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18772 Filed 7–31–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0438]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 31, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0583. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (OMB Control Number 0910–0583)—Revision

I. Background

Since May 29, 1992, when FDA issued a policy statement on foods derived from new plant varieties, FDA has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA early in the development process to discuss possible scientific and regulatory issues that might arise (57 FR 22984). The guidance, entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use,'' continues to foster early communication by encouraging developers to submit to FDA their evaluation of the food safety of their new protein. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of material from that plant variety.

FDA believes that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. The guidance describes the procedures for early food safety evaluation of new proteins in new plant varieties, including bioengineered food plants, and the procedures for communicating with FDA about the safety evaluation.

FDA has recently developed a form that interested persons may use to transmit their submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition. New Form FDA 3666, a draft of which is available at *http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/RegulatorySubmissions/UCM199325.pdf,* is entitled, ''Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation)'' and may be used in lieu of a cover letter for a New Protein Consultation (NPC). Form FDA 3666 prompts a submitter to include certain elements of a NPC in a standard format and helps the respondent organize their submission to focus on the information needed for FDA's safety review. The form, and elements that would be prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway (ESG), or may be submitted in paper format, or as electronic files on physical media with paper signature page. The information is used by FDA to evaluate the food safety of a specific new protein produced by a new plant variety.

II. NPC Information Submitted on Form FDA 3666

The NPC submitted to FDA includes the following information on Form FDA 3666 and in attachments to the form:

A. Introductory Information About the Submission

- Whether the NPC submission is a new submission, or an amendment or supplement to a previously established NPC;
- Whether the submitter has determined that all files provided in an electronic transmission are free of computer viruses;
- The date of the submitter's most recent meeting (if any) with FDA before transmitting a new NPC submission; and
- The date of any correspondence, sent to the submitter by FDA, relevant to an amendment or supplement the submitter is transmitting.

B. Information About the Submitter

- The name of and contact information for the submitter, including the identity of the contact person and the company name (if applicable); and
- The name of and contact information for any agent or attorney who is authorized to act on behalf of the submitter.

C. General Administrative Information

- The title of the submission;
- The format of the submission (i.e., paper, electronic, or electronic with a paper signature page);
- The mode of transmission of any electronic submission (i.e., ESG or transmission on physical media such as CD–ROM or DVD);
- Whether the submitter is referring us to information already in our files;
- Whether the submitter has designated in its submission any information as trade secret or as confidential commercial or financial information; and

• Whether the submitter has attached a redacted copy of some or all of the submission.

D. Information About the New Protein

• The name of the new protein;
• Any requested registry designations for the new protein; and
• The purpose or intended technical effect of the new protein.

E. Information about Genetic Material

• Information about the introduced genetic material (including identity and source).

F. The Scientific Evaluation of the Food Safety of the New Protein

The submitter indicates:

• Whether there is a history of safe use of the new protein in food or feed;
• Whether the submitter has included an assessment of the amino acid similarity between the new protein and known allergens and toxins;
• Whether the submitter has included information about the overall stability of the protein, and the resistance of the protein to enzymatic degradation using appropriate *in vitro* assays; and
• Whether the submitter has included any other information for FDA to consider in evaluating a NPC.

Form FDA 3666 also requires the signature of a responsible official (or agent or attorney) and a list of attachments.

III. Public Comment

In the **Federal Register** of May 15, 2012 (77 FR 28603), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

IV. Burden Estimate

Description of Respondents: The respondents to this collection of information are developers of new plant varieties intended for food use.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Category	FDA Form No. [2]	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
First four data components	Form FDA 3666	20	1	20	4	80
Two other data components	Form FDA 3666	20	1	20	16	320
Total						400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Form FDA 3666 may be submitted electronically via the ESG.

The estimated number of annual responses and average burden per response are based on FDA's experience with early food safety evaluations submitted in the past 3 years. Completing an early food safety evaluation for a new protein from a new plant variety is a one-time burden (one evaluation per new protein). Based on its experience over the past 3 years, FDA estimates that approximately 20 developers will choose to complete an early food safety evaluation for their new plant protein, for a total of 20 responses annually. Many developers of novel plants may choose not to submit an evaluation because the field testing of a plant containing a new protein is conducted in such a way (e.g., on such a small scale, or in such isolated conditions, etc.) that cross-pollination with traditional crops or commingling of plant material is not likely to be an issue. Also, other developers may have previously communicated with FDA about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop.

The early food safety evaluation for new proteins includes six main data components. Four of these data components are easily and quickly obtainable, having to do with the identity and source of the protein. FDA estimates that completing these data components will take about 4 hours per NPC. FDA estimates the reporting burden for the first four data components to be 80 hours (4 hours × 20 responses).

Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis which can be performed using publicly available databases. The other data component involves ''wet'' lab work to assess the new protein's stability and the resistance of the protein to enzymatic degradation using appropriate in vitro assays (protein digestibility study). The paperwork burden of these two data components consists of the time it takes the company to assemble the information on these two data components and include it in a NPC. FDA estimates that completing these data components will take about 16 hours per NPC. FDA estimates the reporting burden for the two other data components to be 320 hours (16 hours × 20 responses). Thus, FDA estimates the total annual hour burden for this collection of information to be 400 hours.

FDA expects that most if not all businesses filing NPCs in the next 3 years will choose to take advantage of the option of electronic submission via the ESG. Thus, the burden estimates in table 1 of this document are based on the expectation of 100 percent participation in the electronic submission process. The opportunity to provide the information in electronic format could reduce the agency's previous estimates for the time to prepare each submission. However, as a conservative approach for the purpose of this analysis, FDA is assuming that the availability of new Form FDA 3666 and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission. While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure (PKI) certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20 to $30.

Dated: July 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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